MEMO TO : X-ray Machine Registrants

FROM : Terry L. O'Clair, P.E.

Director

Division of Air Quality

RE : January 3, 2011 Radiological Health Rules

DATE : January 28, 2011

Beginning January 1, 2011 a new version of the North Dakota Radiological Health Rules (NDRHR) went into effect. This new edition of the rules is the result of several factors. The major influence has been evolving new technology. New types of systems (and subsequent new uses) and a change from film/screen imaging to digital imaging.

The attached document reviews the changes to the NDRHR which affect X-ray machine registrants, assemblers and operators.

You will not be mailed a hardcopy of these rules. The rules are available in two ways, you may access and download a copy from the Radiation Control Program website at the following link, (http://www.ndhealth.gov/aq/RAD/RADRULES/contents.htm) or you may contact this Department by email at xray@nd.gov or by telephone at (701)328-5188 and request a CD containing the rules.

The following list of chapters has been identified as applicable to X-ray machine registrants.

33-10-01	GENERAL PROVISIONS
33-10-02	REGISTRATION OF RADIATION MACHINE FACILITIES AND SERVICES
33-10-04.2	STANDARDS FOR PROTECTION AGAINST RADIATION
33-10-05.1	RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC
	OPERATIONS
33-10-06	X-RAYS IN THE HEATLING ARTS
33-10-08	RADIATION SAFETY REQUIREMENT FOR ANALYTICAL X-RAY
	EQUPMENT
33-10-09	RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS
33-10-10.1	NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS – INSPECTIONS
33-10-11	FEES FOR ISSUANCE OF LICENSE AND REGISTRATION CERTIFICATES
	AND INSEPCTIONS
33-10-15	THERAPETUCI RADIATON MACHINES

TLO/WF:csc

CHANGES TO



FOR X-RAY MACHINE REGISTRANTS

Effective Date

January 1, 2011

RADIATION CONTROL PROGRAM



Division of Air Quality

918 East Divide Avenue, 2nd Floor

Bismarck, ND 58501-1947

Phone: 701-328-5188

FAX: 701-328-5185

Email: X-ray@nd.gov

Changes to the North Dakota Radiological Health Rules (NDRHR) chapters pertaining to facilities with X-ray machines include many organizational modifications (definitions have

been moved, references have been changed and there have been separations and combinations). The adoption by reference to the Code of Federal Regulations (10 CFR) of the US Nuclear Regulatory Commission (NRC) facilitated the opportunity to more readily identify and separate machine produced and material produced ionizing radiation requirements. Some definitions are now included in reference documentation and some are moved from previous chapters and placed within a specific area of practice (specific chapters).

CHAPTER 33-10-01 – GENERAL PROVISIONS

The remaining definitions are those which are not contained in the adopted 10 CFR rules and are associated with more than one chapter of the NDRHR.

CHAPTER 33-10 02 – REGISTRATION OF RADIATION MACHINES FACILITIES AND SERVICES

There are no changes to the requirements.

CHAPTER 33-10-04.2 – STANDARDS FOR PROTECTION AGAINST RADIATION

Section 33-10-04.2-01 contains references for radiation protection requirements which apply to radioactive materials and X-ray machines as referenced in 10 CFR Part 20.

Sections 33-10-04.2-02 through 33-10-04.2-06 are existing X-ray machine specific radiation protection requirements which have now been consolidated, in one location, within this chapter.

CHAPTER 33-10-05.1 – RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

This entire chapter was repealed and now references 10 CFR Part 34.

CHAPTER 33-10-06 - X-RAYS IN THE HEALING ARTS

The term "limited scope X-ray operator" has been replaced with the American Registry of Radiological Technologist (ARRT) term "Limited X-ray Machine Operator (LXMO)" throughout the chapter.

Item 33-10-06-03.1.a(2)(c)[3] eliminates the possibility of a LXMO performing Computed Tomography (CT) procedures under any circumstance.

Section 33-10-06-03 contained requirements dealing with the implementation of operator training and are no longer necessary and were removed.

Paragraph 33-10-06-03.1.a(3) addresses the Continuing Education (CE) requirement mandated by legislative rule and is contained in Appendix K. **Subsection 33-10-06-03.1.c** requires operator identifier to be included in the X-ray log book.

Paragraph 33-10-06-04.5.a(1) contains new half value layer (HVL) requirements for systems manufactured after June 10, 2006.

Section 33-10-06-05 requires fluoroscopic systems manufactured after June 10, 2006 to meet additional specifications for the display of air kerma and air kerma rate. **Section 33-10-06-07** contains additional requirements for new portable handheld dental imaging technology. Due to the nature of this new technology, the operator must remain in the room and therefore is required to wear a lead apron and be monitored for dose. Also, due to the portable nature of this device, this section includes additional device security requirements.

Appendix G The Associate of Science Practical Nurse was added to the list of approved pre-requisite qualifications for Limited Xray Machine Operator training.

Appendix H Limited Xray Machine Operator 2-hour training in pediatrics and 1-hour training in North Dakota Radiation Rules and Regulations has been incorporated into this appendix. This transfers the obligation of this requirement to the training facility.

Appendix I Additional views have been added to the scope of practice for the LXMO.

Appendix K Explains Continuing Education (CE) requirements for operators of Xray systems in the healing arts, excluding dental and veterinary operators.

CHAPTER 33-10-11 – FEES FOR ISSUANCE OF LICENSE AND REGISTRATION CERTIFICATES AND INSPECTIONS

All machine fees are being increased this year and on an annual basis for the next 5 years. Thereafter fees are adjusted annually using the August 31, 12-month Consumer Price Index (CPI). Also the ability to pay by credit card is now available.

CHAPTER 33-10-15 – THERAPEUTIC RADIATION MACHINES

Formerly located within Chapter 6, this new chapter includes previous requirements, establishes one location for therapeutic radiation machine requirements and incorporates recent industry standards. New requirements include more specific identification of training, the establishment and monitoring of a Quality Management (QM) program and mandatory handling of patient overexposure.